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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,811	KOZAK, KENNETH J.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/3/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-29* is/are rejected.

7)☒ Claim(s) *15-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 14-29 are pending.

Claim Objections

1. Claims 15-23 is objected to because of the following informalities: Claims 15-23 depend from canceled claims 1 or 4. Appropriate correction is required.

Double Patenting

1. Claims 17 and 18 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 20 and 21, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 14-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/719,320. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods steps and reagents utilized in the claimed methods and kits are obvious variants one of the other, the copending application reciting a species within the instantly claimed genus of methods that permit the H.pylori antibodies to be cross reactive and the copending claims may not, but utilize reagents in the instant claims that include the reagents of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

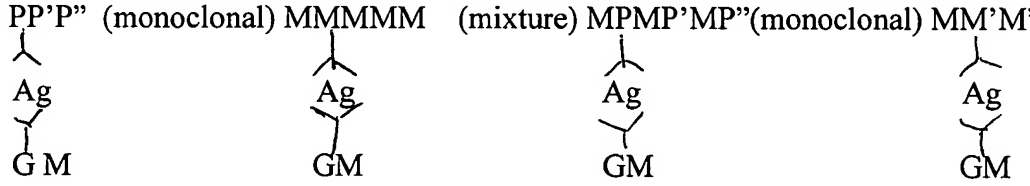
3. Claims 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the fact that the depend from canceled claims 1 or 4.

4. Claims 14-28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

§ 2172.01. The omitted steps are: In light of the following analysis, the specific step of **confirming** the determination of H.pylori antigen is missing.

The examiner is reading the term "specific" in light of the definitions and compositions of antibodies disclosed in the instant Specification. The Specification defines the term "specific" to include a continuum of specificity, to include cross reactivity, in light of the fact that the genus specific monoclonal antibodies bind to both Helicobacter and Campylobacter bacteria. Additionally, the scope of the claims include embodiments pictorially shown immediately below:

P: polyclonal antibody binding; M: monoclonal binding Ag:antigen GenusMonoclonal/CrossReactive: GM



The Polyclonal antibodies are referred to being H.pylori "specific", which defines a continuum of specificities, and not an absolute binding specificity for a single bacterial pathogen, but defines specific binding to its antigen without non-specific binding. All antibodies specifically bind to the antigen to which they were raised, but may also bind to the same antigenic epitope from other sources. Applicant's instant Specification teaches the utilization of ATCC 43504 (whole cell antigen) in the production of Helicobacter pylori specific polyclonal antibodies (Instant Specification 0013). Upon consideration of antigen analysis of H.pylori strains, including strain ATCC 43504, the examiner found Meyer et al (PG-Pub 2003/01800330) to teach the presence of a number of antigens that will induce antibodies that will immunoreact with more than one strain or species of bacteria (see Meyer et al (PG-Pub 2003/01800330, paragraph [0086; 0127; 0137; 0139 and 0273]. The polyclonal antibodies raised to Applicant's whole cell antigen would therefore include cross reactive antibodies (see instant Specification

[005]).

- The first embodiment, polyclonal antibodies, would be present that evidence cross reactive antibodies in the composition, and the GM monoclonal antibody is also cross reactive. This claimed embodiment will detect both Helicobacter and Campylobacter bacteria.

PP'P" / Ag / G

- The second embodiment , monoclonal antibodies, that reacts specifically with a H.pylori antigen and does not exclude reactivity with conserved epitopes in urease or flagella that would result in immunoreactivity reactivity with other species of Helicobacter . The GM monoclonal will cross react with Helicobacter, Campylobacter and Helicobacter pylori. The second embodiment would detect not only Helicobacter pylori, but Helicobacter felis, H. hepaticus and any other Helicobacter species to which the M antibodies would immunoreact, that present a conserved epitope. MMMMM / Ag/ GM

- The third embodiment, MPMP'MP" / Ag/ GM evidences a similar analysis to that of the first and second embodiments set forth above as it is a combination embodiment and therefore would detect Helicobacter species, Helicobacter pylori and Campylobacter species.

- The fourth embodiment, MM'M"/Ag/GM, is similar in analysis to that of the second embodiment as the mixture of monoclonal antibodies are not defined to bind to different antigens, but just be a mixture of monoclonal antibodies which all could immunoreact with the same epitope that is conserved across Helicobacter species and therefore would detect Helicobacter pylori, Helicobacter felis as well as other species that could be found in a fecal sample.

Therefore the claims are missing an essential confirmation step in the process of

determining H.pylori antigen in a human fecal specimen. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 14-29 are rejected under 35 U.S.C. 102(e, effective filing date October 29, 1998) as being anticipated by Reiter et al (US 2004/ 0023316 A1).

Reiter et al disclose the instantly claimed invention directed to a method of detecting Helicobacter pylori antigen (see pages 1 and 3, respectively, [0003], and [0020]) in a human

fecal specimen (see title "stool", and page 4, [0038] "especially of human patients") the method comprising the steps of:

1) dispersing human fecal specimen in a protein based diluent ("skim milk" see page 13, paragraph [154] which contains casein (see US Pat. 6,793958, Brief Summary paragraph 19, ""instead of casein protein, it is possible to use skimmed milk protein"; Detailed Description test paragraph 4 "casein utilized in the present invention is preferably added as skimmed milk powder");

2) contacting the fecal specimen in the diluent with an antibody to form a complex (see page 13, [0154 "ELISA plates were coated for 1 hour at 37o in 100 ul of an mAK solution (2.5 ug antibody/ml carbonate buffer, 0.1M, pH 9.5)"; a plurality of monoclonal antibodies were used, see Table 4, page 13; page 14, [0159 "combination" of monoclonal antibodies]);

3) exposing the complex to a second antibody that is labeled (see page 13, paragraph [0154, column 2, and Table 4]);

4) detecting (streptavidin with POD, produces a blue colored product) the amount of the labeled antibody (biotin labeled) in the complex and in turn determining the presence of H.pylori antigen in the fecal specimen (see page 13, Table 4).

Both the first and second monoclonal antibodies specific were genus specific antibodies, the epitopes to which they bound shown in Table 2, page 12, paragraph [0144]. The urease B subunit epitope (VGEVITR, amino acid sequence for epitope) is present in Helicobacter pylori, H.heilmannii, H. felis, H. hepaticus, H.bizzozeronii, Helicobacter sp. TD1 and Campylobacter pylori (see Swiss-Prot Blast search alignments provided as evidence of the epitope binding specificity for the monoclonal antibodies to be genus specific). Additionally, a second

monoclonal that is a genus specific monoclonal with binding specificity for the alpha subunit of Helicobacter pylori (LPLGRNA, amino acid sequence of epitope), would also immunoreact with this epitope that is present in H. hepaticus and Campylobacter jejuni (see Swiss-Prot Blast search alignments provided as evidence of the epitope binding specificity for the monoclonal antibodies to be genus specific).

Washes were carried out between steps (see page 11, [0142].

(Instant claims 26 and 29) Kits (see [0098] and claims 51-53) that comprise a plurality of monoclonal antibodies, diluents, solid support (see page 8, [0092-0093; 0075]devices, the solid support being defined to include microtiter plates, particles, gold colloidal particles, latex, test strips, to name a few.

5. Claims 14-29 (claims 15-23 are being read as if they depend from independent claim 14) under 35 U.S.C. 102(e) as being anticipated by Larka et al (US Pat. 5,932,430,) .

Larka et al disclose an immunoassay for the determination of H.pylori (see col. 2, lines 16-18) in a sample utilizing first and second antibodies (see claims) , wherein the first antibody either is a polyclonal antibody or mixture of monoclonal and/or polyclonal antibodies specific for H.pylori (see col. 2, lines 47-53) and the second antibody is polyclonal antibody or mixture of monoclonal and/or polyclonal antibodies (see col. 2, lines 47-53) . The disclosed antibodies that immunoreact with H.pylori and are monoclonal antibodies would inherently be genus specific antibodies, especially in light of the fact that the antibodies are taught to not introduce cross-reactivity problems into the assay (see col. 2, line 16) .

Kits were disclosed that comprise the essential immunoassay reagents (see col. 2, lines

42-46). Among the combinations of antibodies for the immunoassay were: H.pylori specific polyclonal antibodies and a mixture of monoclonal antibodies specific to H.pylori

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that □this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure..

2. Helicobacter and Campylobacter are not the same genus of bacteria. The two different genera were established in 1989, when Helicobacter had its name changed from Campylobacter pylori to Helicobacter pylori based upon genetic analysis, ultrastructural analysis and morphological analysis (see Goodwin et al, International Journal of Systematic Bacteriology, October 1989, vol.39(4), pages 397-405) . Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
August 31, 2006

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